

BBS-Bioactive Bone Substitutes Oyj
Company Announcement

BBS-Bioactive Bone Substitutes Plc: BBS-Bioactive Bone Substitutes Plc (BBS) Interim Report 1.1.-30.6.2018 (unaudited)

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Company Announcement 30.8.2018 at 9:00 am

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January-June shortly (comparison season 1-6/2017)

- The quality system ISO 13485 has been updated in accordance with the latest requirements
- An own customized syringe has been designed for the final product
- A prototype replacing the manual filling of the syringes has been constructed
- The preliminary report of the clinical trial has been completed
- In the updated European Commission's product classification manual BBS's ARTEBONE is mentioned as an example, and can be accepted as a medical device class III
- BBS did not have any sales. Other operating income was EUR 2,237 (0,020) million due to accord
- The accords of old loans will improve the result for the period by EUR 2,22 million
- The cash flow from operations was EUR 1,15 (0,424) million
- BBS's cash assets on 30th June 2018 was EUR 2,27 (0,145) million
- The company's financial position strengthened through listing on the NASDAQ First North market places in Helsinki and in Stockholm. EUR 3,5 million new fund was raised for the company in the IPO. The cost of listing during the period was EUR 0,33 million

Key financial figures

1000 euros	1-6/2018	1-6/2017	1-12/2017
Other operating income*	2 237	14	20
Personnel expenses	356	284	603
Depreciation and impairments	112	106	3 163
Other operating expenses	588	170	517
Profit (Loss) of the period	-1 024	-666	-4 466
Cash flow from business operations	-1 153	-424	-1 094
Equity ratio %	42,8	30,0	5,5
Earnings per share €	0,21	-0,16	-1,00
The number of the shares at the end of the period	5 090 520	4 236 901	4 454 001
The average number of the shares during the period	4 904 136	4 157 448	4 305 725

*Includes an accord EUR 2,22 million from the loans

1000 euros	30.6.2018	30.6.2017	31.12.2017
Cash and securities	2 270	145	35

Equity	5 061	3 825	536
Equity and liability total	11 816	12 747	9 669

The equity ratio = equity/equity and liabilities total

Earnings per share = earnings for the period/the average number of the shares during the period

Guidance for 2018

For the year 2018, substantial net sales are not expected to be generated.

Outlook for 2018

BBS will drive forward the CE marking process of the first product and launch sales and marketing preparations.

Pekka Jalovaara, CEO

BBS-Bioactive Bone Substitutes Plc (BBS) is a growing Finnish company that has developed a new bone implant, medical device, for treating of bone traumas, bone losses and bone defects. The company has the headquarters and quality control laboratory in Oulu and the EU-certified production facility at Reisjärvi. The company has a history of over 15 years, during which time the company has developed product and production methods, performed required preclinical and clinical tests, and established a manufacturing line and a quality system for commercial production. The product development phase of a company like BBS is typically 10-15 years and BBS has not been able to fall below this, especially when this is a brand-new product at the interface between a medical device and a medicinal product. Product classification has been challenging and just recently we got a confirmation that our product is acceptable as a medical device. In the updated manual of the European Commission (MANUAL ON BORDERLINE AND CLASSIFICATION IN THE COMMUNITY REGULATORY FRAMEWORK FOR MEDICAL DEVICES), ARTEBONE[®] is an example case and the approval path is the exactly the same that BBS has followed.

Our company still has no turnover, but the CE marking and FDA approval processes required for the product's marketing authorization are currently under way. Sales are expected to begin no later than next year as soon as the CE marking is received. Until now, BBS has been a product development company but is now heading for marketing and sales. Sales are expected to start in the Nordic countries and a few Central European countries, while investing heavily in partners.

ARTEBONE[®] product contains natural bone hard component, tricalcium phosphate mineral granules, as well as proteins including the bone growth factors that are extracted from reindeer bone. The product resorbs from the trauma when it heals. Currently there are products with only one of these components, but BBS has managed to combine these two. Our first product is a ready-to-use paste in the syringe so there is no need to make any mixing on the operating table, which is typical for competing products. ARTEBONE[®] product is based on its ingredients comparable to bank bone or human DBM (Demineralized Bone Matrix) products. DBM products have been found to poorly induce the formation of new bone. In addition, the quality of human-derived products may vary greatly depending on the age and health of the donor. The reindeer bone protein extract in ARTEBONE[®] is very homogeneous because bones from about 70 reindeer are used on one batch. Reindeer bone protein extract has been found safe in preclinical trials and no human viral diseases can be transmitted to patients. In clinical trial, ARTEBONE[®] has proven to be safe and functional.

Based on the studies carried out, the ARTEBONE® product can in future replace the most common currently used own bone grafts in the treatment of bone problems. This brings significant saving to the society, hospitals and patients. Own bone graft needs to be taken from your own body, typically from the iliac crest and this means additional surgery that takes time up to an hour. Surgical harvesting of bone also involves the risk of complications. With ARTEBONE® only one surgery is needed instead of two. Therefore, the hospitalization time is shortened, and the patient recovers more quickly.

Furthermore, our product is ecological because we use renewable materials in our premium products to promote people's health.

The objective of the Offering was primarily to enable BBS to raise funds to complete ARTEBONE®'s ongoing application processes for the CE marking and FDA approval, begin commercial production and the commercialization of the product. Funds are also needed to continue product development, develop and maintain the patent portfolio, ensure sufficient self-financing for growth investments in accordance with our company's strategy and hire additional staff for sales and marketing.

Funds raised in the IPO are used to implement the above-mentioned issues. The main objective is to complete the licensing processes, and especially sales and organizational development.

Our first short-term goal is to get marketing approvals and to open sales in the Nordic countries and Europe. One of our main goals is to find a big partner to ensure global access to the market. Large companies in the industry do not do their own product development; instead they observe the small product development companies.

FINANCIAL REVIEW 1th January - 30th June, 2018

Overall

BBS has made for the period 1th January - 30th June 2018 the consolidated financial statement for the first time. BBS owns 100% of the subsidiary Bio Bones Oy, which owns the real estate for production in Reisjärvi. Bio Bones has no other business.

Operating income and development costs

BBS did not have any significant net sales during the review period and the corresponding period of the previous year. In other income the Tekes decision not to collect old product development loans of EUR 2,22 million has been recorded.

Financing and investments

The company's cash assets at 30th June 2018 were EUR 2,27 million. The company estimates the current funding is enough for about one year from the date of this release.

The groups cash flow from operations was EUR 1,153 (-0,42) million in the review period.

Acquisitions and directed share issues

No acquisitions were made during the review period.

BBS was listed in February 2018 on the NASDAQ First North list in Helsinki and Stockholm. Issue of the IPO raised a gross of EUR 3,5 million in assets. The cost of the listing was EUR 0,33 million during the review period.

Balance sheet

The consolidated balance sheet total on 30th June 2018 was EUR 11,816 (12,747) million. On the 30th June 2018 the company had a short-term debts EUR 0,53 (0,72) million, long-term loans to financial institutions EUR 6,22 (8,92) million, capital loans of EUR 0,176 (0,95) million. Financial income and expenses amounted to EUR 0,051 (0,050) million.

Equity

Equity on 30th June 2018 was EUR 5,06 (3,82) million. In the financial statement at December 2017, the shareholders equity was EUR 0,54 million. In the financial year 2017, for the activation of product development was made a write-off of EUR 3,5 million due to the project phase deemed unnecessary for the current product. During the review period on 30th June 2018, the listing on the stock exchange and the accord of the old loans raised the shareholder's equity.

Staff and administration

The number of employees was 12 at the end of review period on 30th June 2018. Members of the board were Jarmo Halonen (chairman), Päivi Ylä-Kolu, Auvo Kaikkonen, Tomi Numminen, Pekka Jalovaara and Hannu Säynäjäkangas. Pekka Jalovaara is acting as the CEO.

The annual general meeting 2018

The annual general meeting (AGM) of BBS was held in Oulu on 28th March 2018.

The AGM approved the financial statements for 2017 and discharged the members of the board of directors and the CEO from liability. The AGM decided, in accordance with the proposal of the board of directors, that no dividend be paid for the financial year 2017 and that the loss for the financial year is recorded in the profit/loss account.

The AGM approved the remuneration of board members for EUR 500 and for the chairman EUR 750 per meeting.

The AGM decided that a reasonable fee would be paid to the auditor in accordance with the invoice approved by the company. Auditing society Ernst&Young Oy was elected as the auditor of BBS, with KHT Juhani Rönkkö as the principal auditor.

Share-based incentive plan

The company has a valid stock option program for 2012 approved by the AGM in 18th July 2012. The board of directors has decided on options for the 2th January 2013 as authorized by the AGM. Options have been issued to key personnel and by each option can subscribe for one share at the price of one euro until 31th December 2019. The board of directors, on 9th January 2018, continued the subscribe period until 31th December 2023. Stock options may be issued up to 170 000 new shares and this has no perceptible impact on the earnings per share.

Risks and uncertainties

The company's listing and debt accord have lowered the near future financial risk. The European Commission's manual on medical devices reduced the risk associated with the classification of ARTEBONE®. According to the company's management, there are no significant changes in the risks and uncertainties associated with the business of BBS during the first half of 2018.

Significant risk and uncertainties related to the business of BBS have been announced in the listing brochure of 30th January 2018, which can be accessed on the website at www.bbs-artebone.fi.

Shares and shareholders

The BBS's market capitalization at the end of the review period on 30th June 2018 was EUR 19,6 million. The closing price of the share on 30th June 2018 was EUR 3,85. The highest price for the review period was EUR 4,72 and the lowest was EUR 3,65.

BBS had 1163 registered shareholders, including a register of shareholders dated 30th June 2018.

The BBS's board of directors and the CEO held 30th June 2018 total of 543 650 (532 850) shares including shares held through controlled companies, i.e. 10,7% of the company's shares. Information about the company's insider trading in the company's shares is published on the company's website.

Event after the review period

The company has no relevant reporting after the review period.

During the review period no capitalized and product investments have been made in balance sheet.

Half-year accounting principles

The half-yearly review has been prepared in accordance with the Finnish Accounting Act and rules of the First North marketplace. Figures for the half-yearly review are unaudited.

Financial information 2019

The financial statement bulletin for January-December 2018 will be published on 22th March 2019, 9 am.

ATTACHMENTS:

Financial Statement 30th June 2018
Cash Flow Statement 30th June 2018
Statement of changes in equity

MORE INFORMATION:

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BBS-Bioactive Bone Substitutes Plc ("BBS") is the health technology company operating since 2003. Before that there was a background of seven years of medical research in the University of Oulu. We have developed a new product for healing of difficult bone fractures and for solving the problems in bone healing. Our mission is to offer new generation medicinal products for the orthopedic surgery. The research and development in the field of medicine requires perseverance and courage to develop new things. We have over 20 years of expertise in this. Our operations are characterised by top expertise, innovativeness and dedicated and committed employees. The ARTEBONE ®product is ready and the application process for the CE-mark has been initiated. BBS is the company having its headquarters in Oulu. We have our own production plant located in Reisjärvi and it is approved by FIMEA. More information: www.bbs-artebone.fi.

DISTRIBUTION:

Nasdaq Helsinki Oy

Nasdaq Stockholm AB

Main media

Attachments:

[BBS interim report H1 2018 attachment.pdf](#)